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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/729,541

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D. Bruce Modesitt

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1905

57360

7590

05/01/2009

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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

05/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/729,541	Applicant(s) MODESITT ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/23/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-11, 14-18, 20, 21, 23-25, 28, 29, 32-35, and 38-45 is/are rejected.
- 7) ☒ Claim(s) 7, 12, 13, 22, 26, 27, 30, 31, 36 and 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 23, 2009 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3, 5, 6, 8-11, 14-17, 20, 21, 23-25, 28, 29, and 32-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Shaknovich (5,749,890). Shaknovich discloses, at least in figures 6-14, a device and a method with the device for closing an opening (ostium) in a tissue or blood vessel, where the device and method include a shaft (4) having a proximal end portion and a distal end portion, a foot (11) disposed on the distal end of the shaft that is spaced apart from the proximal end portion and is movable with respect to the shaft, a foot receptacle (lumen at the distal portion of

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element 4, in the vicinity of element 6) disposed at the distal end portion of the shaft and at least a portion of the foot receptacle (402) passing through the shaft (440); a flexible guidebody (17) coupled to the distal end portion of the shaft and extending beyond the foot receptacle and defining a guidewire (14) lumen or a suture storage lumen, where the foot is movable from within the foot receptacle to a deployed position with the foot extending laterally from the shaft across the distal end portion of the shaft (when expanded as seen in fig. 14) and at least in part external to the foot receptacle (at the distal end of the foot), where the flexible guide body (17) defines a guidewire entry port at its distal end (an opening at the distal end) and an exit port proximal to the entry port (an opening at the proximal end), where a portion of the shaft curves such that the flexible guide body extends from the shaft at an angle relative to an axis of the shaft, where the device includes a length of suture (14) supported by the foot, where the flexible guidebody (17) defines a lumen with the suture extending therethrough, where the method includes partially withdrawing the flexible guidebody from a tissue opening to reduce a flow of blood through the opening (i.e., the guidebody is moved, so that the expanded foot obstructs the opening, as seen in fig. 14); where the method includes moving the foot from a parked position to a deployed position, where the opening is accessed through subcutaneous tissue; where the flexible guidebody extends from the shaft at an angle relative to an axis of the shaft and positioned coaxially within the blood vessel, while the shaft is positioned coaxially within a tissue tract, and where the foot is aligned with the blood vessel when in the deployed position.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaknovich (5,749,890) in view of Horzewski et al (4,748,982). Shaknovich discloses the invention substantially as claimed, but does not disclose a guidewire exit port situated at a location distal to the distal end of the shaft. Horzewski et al. teach, at least in figures 1 and 6 and in col. 4, lines 45-57 and col. 5, lines 9-17; a flexible guidebody (11) including guidewire exit port (33) situated at a location distal to the distal end of a shaft (a "guiding catheter"). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Horzewski et al., to modify the flexible guidebody of Shaknovich, so that a guidewire exit port is situated as claimed. Such a modification would allow convenient insertion or removal of a guidewire into the guidebody and would allow rapid exchange of dilation catheters as necessary.

5. Claims 38, 40, and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradley et al. (5,374,275) in view of Klein et al. (6,517,553), and further in view of Moore et al. (5,531,700). Bradley et al. disclose the invention substantially as claimed. Bradley et al. disclose, at least in figures 2, 6, and 7; a device for closing an opening in tissue, where the device includes a shaft (12) having a proximal end portion, a distal end portion, a foot receptacle (66), and a least one pin

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spaced from the proximal end portion (unlabeled pin connected to elements 72 and 24); a foot (28) having at least one slot (at interface with 72) or with respect to claims 43-45, the combination of 72, 74 and 28; the at least one slot being connected to at least one pin at the distal end portion of the shaft, and the foot being movable with respect to the shaft; and a guidebody extending from the distal end portion of the shaft (the conical tip of the shaft as seen in figures 6 and 7), where the foot is rotationally movable about the at least one pin, where the foot has at least one receptacle (28 with respect to claims 43-45) with a slot oriented with respect to a surface of the at least one receptacle, and where the slot extends substantially tangential to the surface of the at least one receptacle and extends laterally through (i.e., the side of) the foot. However, Bradley et al. do not disclose that the guidebody is flexible and is configured to receive a guidewire. Klein et al. teach, at least in figures 4A and 8 and col. 8, lines 49-55 and col. 10, line 65 to col. 11, line 2; a device for closing an opening in tissue, where the device includes a flexible guidebody (66) configured to receive a guidewire. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Klein et al., to modify the guidebody of Bradley et al., so that it is flexible and configured to receive a guidewire. Such modifications would allow the device of Bradley et al. to penetrate into and be guided through a hollow organ, such as a blood vessel, without tearing the penetration and without damaging the inner wall of the organ. An opening in the hollow organ can then be closed with the device of Bradley et al.

However, Bradley et al. in view of Klein et al. do not disclose that the flexible guidebody includes a guidewire exit port in its sidewall. Moore et al. teach, at least in

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figures 3A and 3B and col. 8, lines 1-8; a flexible guidebody (28) including a guidewire exit port (e.g., 24) in its sidewall. It would have been obvious to one having ordinary skill in the art at the time the invention was made, to modify the device of Bradley et al. in view of Klein et al., so that it includes a guidewire exit port in its sidewall. Such a modification would allow easy removal of the device from tissue over the guidewire because of a short region of engagement with the guidewire (relative to a longer region of engagement as taught by Klein et al.).

6. Claims 38, 39, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer et al. (5,368,601) in view of Klein et al. (6,517,553), and further in view of Moore et al. (5,531,700). Sauer et al. disclose the invention substantially as claimed. Sauer et al. disclose, at least in figures 1-5; a device for closing an opening in tissue, where the device includes a shaft (12) having a proximal end portion, a distal end portion, a foot (70 or 72) having at least one slot (82 or 84); the at least one slot being connected to at least one pin (56, 58 or 98 via suture 94) at the distal end portion of the shaft, and the foot being movable with respect to the shaft; where the slot is axially movable with respect to the at least one pin, where the shaft has a foot receptacle (50 or 52), and where the foot is slidably received within the receptacle. However, Sauer et al. do not disclose a flexible guidebody configured to receive a guidewire that extends from the distal end of the shaft. Klein et al. teach, at least in figures 4A and 8 and col. 8, lines 49-55 and col. 10, line 65 to col. 11, line 2; a device for closing an opening in tissue, where the device includes a flexible guidebody (66) configured to receive a guidewire and extending from the distal end of a shaft. It would

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have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Klein et al., to modify the shaft of Sauer et al., so that it includes a flexible guidebody configured to receive a guidewire. Such modifications would allow the device of Sauer et al. to penetrate into and be guided through a hollow organ, such as a blood vessel, without tearing the penetration and without damaging the inner wall of the organ. An opening in the hollow organ can then be closed with the device of Sauer et al.

However, Sauer et al. in view of Klein et al. do not disclose that the flexible guidebody includes a guidewire exit port in its sidewall. Moore et al. teach, at least in figures 3A and 3B and col. 8, lines 1-8; a flexible guidebody (28) including a guidewire exit port (e.g., 24) in its sidewall. It would have been obvious to one having ordinary skill in the art at the time the invention was made, to modify the device of Sauer et al. in view of Klein et al., so that it includes a guidewire exit port in its sidewall. Such a modification would allow easy removal of the device from tissue over the guidewire because of a short region of engagement with the guidewire (relative to a longer region of engagement as taught by Klein et al.).

Allowable Subject Matter

7. Claims 7, 12, 13, 22, 26, 27, 30, 31, 36, and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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8. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a device and a method with the device for closing an opening in a tissue, where the device and method include, inter alia, a shaft, a foot receptacle, a foot movable from within the foot receptacle to a deployed position at least in part external to the foot receptacle and extending laterally across the distal end portion of the shaft, a flexible guidebody, and a needle advanceable from the shaft through tissue and to the foot in the deployed position, and where the method includes positioning a suture loop across the opening after a suture has been advanced through tissue along a needle path.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

9. Applicant's arguments with respect to claims 1-6, 8-11, 14-18, 20, 21, 23-25, 28, 29, 32-35, and 38-45 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773